REMARKS

This amendment is responsive to the Non-Final Office Action of May 28, 2008. Reconsideration and allowance of claims 1, 5-13, 15-18, and 22-29 are requested.

Status of the Claims

Claims 1, 5-13, 15-18, and 22-29 are pending.

Claims 2-4 and 14 stand withdrawn.

Claims 19-21 were previously cancelled, without prejudice and disclaimer.

No amendments to the claims are made in this response.

The Office Action

Claims 1, 5-13, 15-18, and 22-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,252,720 to Foster, as modified by *Ernst and Race*, and further modified by U.S. Application No. 10/467,591 to Kritzler.

The Present Application

Prions are resistant to many conventional treatment processes used for destruction of microorganisms. Their behavior also differs in many cases to that of conventional proteins. In particular, conformational changes in the structure of prions in various treatments results in a β-sheet structure which is highly resistant to degradation.

The present inventors have found that a treatment in which one or more phenols is combined with an inorganic salt, e.g., sodium chloride, can inactivate prions on a body.

The References of Record

The Foster reference discloses a method for removing contamination from ion-exchange chromatography columns. Foster uses sodium chloride solution to elute and remove prions from the column (col. 3, lines 41-44) through a type of ion exchange mechanism (col. 4, lines 31-33). The prions are not destroyed. Specifically, Foster notes that material eluted during the first 2M sodium chloride wash was subsequently found to have high prion infectivity (col. 6, lines 9-30).

The Ernst and Race reference discloses treating a scrapie-infected hamster brain homogenate with LpH. As mentioned in the Ernst and Race article, LpH is an

aqueous acid phenolic disinfectant which contains o-benzyl-p-chlorophenol at 6.1%, as well as p-tertiary amylphenol at 3%, and phenylphenol at 0.5%.

Kritzler, et al. discloses methods for treating a surface suspension or solution contaminated with prion protein with enzymes. In paragraph 41, Kritzler discloses that certain surfactants tend to bind to proteins and initiate unfolding of their tertiary structure. In paragraph 42 it is noted that inorganic salts can induce conformational transitions in proteins. These paragraphs detail the understanding about proteins in general and not about prion proteinaceous material. It can be seen from Table 1 that these general assumptions do not apply to prions (as represented by models of proteins such as bovine albumin with high globulin content).

The Claims Distinguish Patentably Over the References of Record

Claim 1 calls for a method of treating a body which is contaminated with prions. The method includes contacting the body with a composition comprising a phenol and a soluble inorganic salt to inactivate prions on the body.

The references cited, alone or in combination, do not suggest such a method.

The Foster reference discloses a method for removing contamination from ion-exchange chromatography columns. Foster uses a sodium chloride solution to elute and remove prions from the column (col. 3, lines 41-44) through a type of ion exchange mechanism (col. 4, lines 31-33). Foster requires an ion exchange method capable of preferential uptake of anions from sodium chloride leading to release of prions. There is, however, no suggestion that Foster is enabling for substrates other than anion exchange columns or that the sodium chloride could have any effect on substrates which do not facilitate ion exchange, such as metal surgical instruments. Moreover, the prions are not destroyed. Specifically, Foster notes that material eluted during the first 2M sodium chloride wash was subsequently found to have high prion infectivity (col. 6, lines 9-30).

Ernst & Race (1993) discloses treating a scrapie-infected hamster brain homogenate with LpH. There is no suggestion in this reference that the composition include a soluble inorganic salt. Ernst & Race purports to be a complete solution to the scrapie infection problem and provides no motivation or reason to incorporate an inorganic salt.

Kritzler, et al. discloses methods for treating a surface suspension or solution contaminated with prion protein with enzymes. In paragraph 0041, Kritzler discloses that certain surfactants tend to bind to proteins and initiate unfolding of their tertiary structure. In paragraph 0042, it is noted that inorganic salts can induce conformational transitions in proteins. These paragraphs detail the understanding about proteins in general and not about prion proteins. There is no suggestion in Foster or Kritzler that one should add enzymes to an ion exchange column, or what one might expect to achieve by such an addition. Foster satisfactorily removes prions from the ion exchange column. Neither Foster nor Kritzler lead one to believe that unfolding the tertiary structure would provide a beneficial effect in the prion removal technique of Foster.

In sum, the references alone or in combination, do not suggest a method for the treatment of a body which is contaminated with prions, which includes contacting a body with a composition comprising a phenol and a soluble inorganic salt, such as sodium chloride, to inactivate prions on the body. The Examiner argues that there would have been "a reasonable expectation of success given the taught success of each of the applied references in inactivating prion proteins." However, as noted above, the prions are not destroyed by Foster's salt, but retain high reactivity. Thus, there would have been no expectation that combining the references would lead to success.

The present inventors have found that an inorganic salt, used in combination with one or more phenols, improves the effectiveness of the phenol, especially at low pH. This is believed to be due, at least in part, to the effects on the phenol solubility. This is not taught or suggested by the references.

Accordingly, it is submitted that claim 1, and claims 5-9, 15-16, 18, 22, and 25-28 dependent therefrom, are patentable over the cited references.

Claim 11 calls for a method of treating a body which is contaminated with prions which includes contacting the body with a composition comprising a phenol and a soluble inorganic salt to inactivate prions on the body, the soluble inorganic salt including sodium chloride.

The references of record do not suggest such a method. The salt treatment method taught by Foster does not destroy prions. There is no suggestion for use of sodium chloride in a phenol-based disinfectant, such as LpH, as taught by Ernst and Race. Nor is there any suggestion that the salts proposed by Foster would be useful as

agents favoring unfolding in Kritzler's system. There is no suggestion in Foster that the prions undergo conformational unfolding in the process.

Accordingly, it is submitted that claim 11, and claims 12 and 17 dependent therefrom, are patentable over the cited references.

Claim 13 calls for a method of treating a body which is contaminated with prions. The method includes contacting the body with a composition comprising a phenol to inactivate prions on the body. The phenol includes *o*-phenylphenol and *o*-benzyl-*p*-chlorophenol in a solution that includes brine.

The references do not suggest such a method. None of the references, with the exception of Ernst and Race, suggests treatment with phenol that includes *o*-phenylphenol and *o*-benzyl-*p*-chlorophenol. There is no suggestion in Ernst and Race that such phenols be used in combination with brine. Foster teaches that salt does not destroy infectivity. Kritzler does not suggest that prions undergo conformational changes in the presence of brine nor suggest that such a conformational change, if it were to occur, would have on prion infectivity. Thus, one of ordinary skill in the art would not expect brine to have any effect on an acidic phenol such as *o*-phenylphenol and *o*-benzyl-*p*-chlorophenol.

Accordingly, it is submitted that claim 13 distinguishes patentably over the references of record.

Claim 23 calls for a method of treating a body which is contaminated with prions that includes contacting the body with a composition comprising at least one phenol, the composition comprising a phenol concentration of at least 0.005M and an inorganic salt which is present at a concentration of at least 2% by weight, the phenol including at least one of the group consisting of *p*-chloro-*m*-xylenol; thymol; triclosan; 4-chloro, 3-methylphenol; pentachlorophenol; hexachlorophene; 2,2-methyl-bis(4-chlorophenol); *p*-phenylphenol; 2,3-dimethylphenol; 3,5-dimethoxyphenol; 2,6-dimethoxyphenol; *o*-phenylphenol; *p*-tertiary-amylphenol; *o*-benzyl-*p*-chlorophenol; *p*-chloro, *m*-cresol; *o*-cresol; p-cresol; 2,2-methylenebis(*p*-chlorophenol); 3,4-dihydroxybenzoic acid; *p*-hydroxybenzoic acid; caffeic acid; protocatechuic acid; *p*-nitrophenol; 3-phenolphenol; 2,3-dimethoxyphenol; 2,2-methoxy-bis(4-chloro-phenol); and para-phenylphenol.

The references of record do not suggest treating a body with one or more of the above-mentioned phenols and an inorganic salt at a concentration of at least 2%. The salt treatment method taught by Foster does not destroy prions. Thus, there

is no suggestion for use of sodium chloride in a phenol-based disinfectant, such as LpH, as taught by Ernst and Race. Nor is there any suggestion that the salts proposed by Foster would be useful as agents favoring unfolding in Kritzler's system. There is no suggestion in Foster that the prions undergo conformational unfolding in the process.

Accordingly, it is submitted that claim 23, and claim 24 dependent therefrom, distinguish patentably and unobviously over the references of record.

Claim 29 calls for a method of treating a body which is contaminated with prions. The method includes contacting the body with a composition to inactivate prions on the body. The composition includes a phenol, a cosolvent, water, and a surfactant selected from the group consisting of sulphonic acids, sulfonates, and combinations thereof.

In paragraph 0041, Kritzler discloses that certain surfactants tend to bind to proteins and initiate unfolding of their tertiary structure. This paragraph, however, details the understanding about proteins in general and not about prion proteins. There is no suggestion that detergents affect conformational change in prions or have any effect on the infectivity. Nor is there any suggestion that they should be used in combination with phenols.

Thus, it would not have been obvious, in view of the cited references, to contact a body with a composition which includes a phenol, a cosolvent, water, and a surfactant selected from the group consisting of sulphonic acids, sulfonates, and combinations thereof.

Accordingly, it is submitted that claim 29, and claim 10 dependent therefrom, distinguish over the references of record.

☒ Remaining Claims, as delineated below:

(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT LESS HIGHEST NUMBER PREVIOUSLY PAID FOR		(3) NUMBER EXTRA
TOTAL CLAIMS	**26**	**- 26 =**	**0**
INDEPENDENT CLAIMS	**5**	**- 5 =**	**0**

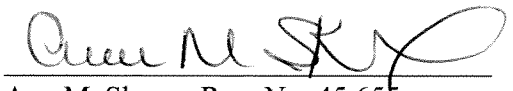
CONCLUSION

For the reasons set forth above, it is submitted that claims 1, 5-13, 15-18, and 22-29 (all examined claims) distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is requested to telephone the undersigned at (216) 861-5582.

Respectfully submitted,

FAY SHARPE LLP



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